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PerkinElmer Life and Analytical Sciences
Wallac Oy
P.O. Box 10
FIN-20101 Turku, Finland
Phone: +358 - (0)2 - 267 8111
Fax: +358 - (0)2 - 267 8357
http://www.perkinelmer.com

SEP 3 0 2004

K042425

510(k) SUMMARY
(as required by 21 CFR 807.92)

The assigned 510(k) number is:

Submitted by: Gunnel Laaksonen
Regulatory Affairs Manager
Wallac Oy
Mustionkatu 6, 20750 Turku
P.O. Box 10, 20101 Turku
Finland

Device Name: AutoDELFIA® Neonatal 17 α-OH-progesterone kit

Common Name: Fluoroimmunoassay, 17-hydroxyprogesterone

Classification: Radioimmunoassay, 17-hydroxyprogesterone
Class I per 21 CFR § 862.1395

Product Code: JLX

Predicate Device: DELFIA® / AutoDELFIA® Neonatal 17 α-OH-progesterone kit, K912026/ K935047

Device Description:

The AutoDELFIA Neonatal 17α-OH-progesterone (17-OHP) assay is a solid phase, time-resolved fluoroimmunoassay based on the competition between europium-labeled 17-OHP and sample 17-OHP for a limited number of binding sites on 17-OHP specific polyclonal antibodies (derived from rabbit). Danazol facilitates the release of 17-OHP from the binding proteins. A second antibody, directed against rabbit IgG, is coated to the solid phase, giving convenient separation of the antibody-bound and free antigen.

Enhancement Solution dissociates europium ions from the labeled antiserum into solution, where they form highly fluorescent chelates with components of the Enhancement Solution. The fluorescence in each well is then measured. The fluorescence of each sample is inversely proportional to the quantity of 17-OHP in the sample.

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Indications for Use:

The AutoDELFIA Neonatal 17α-OH-progesterone kit is intended for the quantitative determination of 17α-OH-progesterone in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the 1235 AutoDELFIA automatic immunoassay system.

Sustantial Equivalence:

The modified AutoDELFIA Neonatal 17α-OH-progesterone kit has the same intended use and is based on the same assay principle as the predicate DELFIA / AutoDELFIA Neonatal17α-OH-progesterone kits (K912026 / K935047).

The performance of the modified AutoDELFIA Neonatal 17α-OH-progesterone kit was tested both by carrying out in-house studies and by studies in neonatal screening laboratories. The performance of the modified kit was found to be equivalent with the predicate AutoDELFIA Neonatal 17α-OH-progesterone kit and suitable for its intended use.

In summary, the AutoDELFIA Neonatal 17α-OH-progesterone kit described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Gunnel Laaksonen
Manager of Regulatory Affairs
Wallac Oy
P.O. Box 10
FIN-20101 Turku, Finland

SEP 3 0 2004

Re: k042425
Trade/Device Name: AutoDELFIA® Neonatal 17 *a*- OH- progesterone kit
Regulation Number: 21 CFR 862.1395
Regulation Name: 17-Hydroxyprogesterone test system
Regulatory Class: Class I
Product Code: JLX
Dated: August 31, 2004
Received: September 8, 2004

Dear Mr. Laaksonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K042425

Device Name: AutoDELFIA® Neonatal 17 α-OH-progesterone kit

Indications For Use: This kit is intended for the quantitative determination of 17 α- OH-progesterone in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the 1235 AutoDELFIA automatic immunoassay system.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

K042425